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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request; The Genetic Testing Registry (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more

information on the proposed project, contact: Taunton Paine, Director, Division of Scientific Data Sharing Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 631, Bethesda, MD 20892, or call non-toll - free number (301) 496–9838, or Email your request, including your address to: *SciencePolicy@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on September 7, 2021, page 50140 (86 FR 50140) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.
The Office of the Director (OD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: The Genetic Testing Registry, 0925-0651, Expiration Date 11/30/21-EXTENSION, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Clinical laboratory tests are available for more than 18,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional

research is needed. The GTR now also has tests for microbes like for SARS-CoV-2 to diagnose COVID-19.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,299.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hour
Laboratory Personnel Using Bulk Submission	Minimal Fields	11	16	18/60	53
	Optional Fields	250	16	17/60	1133
Laboratory Personnel Not Using Bulk Submission	Minimal Fields	84	16	30/60	672
	Optional Fields	57	16	29/60	441
Total		402	6432		2,299

Dated: November 18, 2021.

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Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

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